

## REMARKS

### Status of the Claims

Claims 1-18 are pending. Claims 1-18 stand rejected. Claims 1 and 10 are amended. No claims are canceled. No new matter has been added.

### Amendments to the claims

Claim 1 is amended to overcome rejections under 35 U.S.C. 112, first & second paragraphs, as discussed *infra*. Claim 10 is amended to overcome rejection under 35 U.S.C. 112, second paragraph, as discussed *infra*. Claims 2-3 and 11-12 are amended to simplify claim language about the diameters of the tissue cores. No new matter is added.

### Rejection under 35 U.S.C. 112, first paragraph

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as non-enabled. Applicants traverse this rejection.

The Examiner argues that the term "oil" is extremely broad and that Applicants do not teach what oils are useful in the instant process nor give guidance on how to select an appropriate oil that would be effective in the instant process. Considering the vast number of substances that are considered "oils" it would require undue experimentation to make and use the invention as claimed. Applicants respectfully disagree.

Applicants submit that the specification does teach what oils are useful in making the frozen tissue array of the instant invention. The specification teaches that the oil must have a freezing point, e.g., as low as  $-10^{\circ}\text{C}$ , which must be lower than the freezing point of the embedding compound used in the recipient frame and is used to lock the frozen tissue cores. Additionally, the specification provides one of ordinary skill in the art with guidance as to what would be an appropriate oil by identifying PROTECTIVE OIL® and describing its characteristics (pg. 19, ll. 6-15).

Applicants submit, that given this guidance, one of ordinary skill in the art would be able to select an appropriate oil to use in preparing a frozen tissue array without undue

experimentation. Furthermore, one of ordinary skill in this art would know which oils would be standard in the art or could find the characteristics of such oils from standard references and, furthermore would know that any oil selected must meet the requirements disclosed. Accordingly, in view of these arguments presented, Applicants respectfully request that the rejection of claims 1-18 under 35 U.S.C. 112, first paragraph, be withdrawn.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants traverse this rejection.

The Examiner argues that the intended scope is unclear and indefinite because "oil" is an extremely broad term. As discussed *supra*, the specification teaches what oils are useful and within the context of the claims one of ordinary skill in the art would be able to select an appropriate oil because the oil is used in a preparation of a frozen tissue array, such arrays well known in the art, and the oil is characterized by its freezing point.

The Examiner argues that an essential embedding step is omitted. Applicants have amended claims 1 and 10 to recite that the frozen tissue core is selected from a frozen tissue sample embedded within a donor block and further amended claim 1 to recite that the donor block is held a temperature less than the freezing point of the frozen tissue as is recited in claim 10 (pg. 18, ll. 17-20). Applicants submit that the tissue may be embedded in the donor block and frozen in any manner standard in the art.

A key aspect of the instant invention is that the frozen tissue cores are not embedded as in a standard paraffin array (pg. 13, ll. 9-13), but are locked within compartments within a recipient block, that is formed from an embedding material (pg. 14, ll. 6-7), by the oil added to the compartments. The frozen tissue cores are not embedded within the embedding material of the recipient block nor within paraffin, but are locked into compartments within the recipient block by the oil added thereto upon freezing the oil (pg. 18, ll. 20-21). The method steps of inserting the frozen tissue cores into the recipient block and adding the oil to the compartments in the recipient block or vice versa and cooling the recipient block containing the frozen tissue cores and the oil comprises "locking"

the frozen tissue cores within the compartments to form a frozen tissue array and not embedding them therein (pg. 18, ll. 17 to pg. 19, ll. 20).

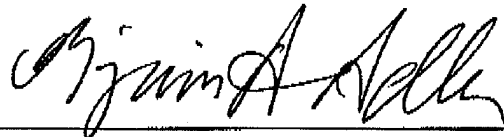
Technically, the tissue cores are embedded within the frozen oil. However, it is inherent in the art that embedding a tissue sample requires heating an embedding medium to liquify it in order to embed the tissue sample therein with subsequent solidifying of the embedding medium. Such temperatures would melt the frozen tissue cores and is not what Applicants method requires. "Locking" the frozen tissue cores as recited in the claims and taught in the specification are distinct from such an embedding procedure.

The Examiner states that the phrase "without melting the tissue cores" in claims 1 and 10 is confusing because one can't tell if the phrase is simply redundant or if there is more to the invention. Applicants have deleted this phrase from claims 1 and 10. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 1-18 under 35 U.S.C. 112, second paragraph, be withdrawn.

This is intended to be a complete response to the Office Action mailed October 3, 2003. If any issues remain, the Examiner is requested to telephone the attorney of record for immediate resolution. Applicants believe no fees are due, however, should Applicant be in error, debit any fees due from Deposit Account No. 07-1185 on which the attorney of record is allowed to draw.

Respectfully submitted,

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